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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,149	11/17/2003	Robert H. Getzenberg	076333-0331	9439

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Stephen B. Maebius
Foley & Lardner
Washington Harbour
3000 K Street, N.W., Suite 500
Washington, DC 20007-5143

EXAMINER	
REDDIG, PETER J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/713,149	GETZENBERG, ROBERT H.	
	Examiner	Art Unit	
	Peter J. Reddig	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-16 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-16 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claim 14-17 been renumbered 13-16.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1, drawn to an antibody directed against RCCA-1 or immunogenic fragment thereof, classified in class 530, subclass 387.1.

II. Claim 1, drawn to an antibody directed against RCCA-2 or immunogenic fragment thereof, classified in class 530, subclass 387.1.

III. Claim 1, drawn to an antibody directed against RCCA-3 or immunogenic fragment thereof, classified in class 530, subclass 387.1.

IV. Claim 1, drawn to an antibody directed against RCCA-4 or immunogenic fragment thereof, classified in class 530, subclass 387.1.

V. Claim 1, drawn to an antibody directed against RCCA-5 or immunogenic fragment thereof, classified in class 530, subclass 387.1.

It is noted for Applicant's convenience that this is a requirement for the election of a Group for examination NOT a requirement for an election of species because although the claims are presented in Markush format, the claims are drawn to multiple agents which do not share, as

a whole, a substantial structural feature disclosed as being essential to their utility. Thus, the analysis of the claims, for restriction purposes, is subject to the findings of the court wherein the court found that unity of invention exists where entities included within a Markush group share a substantial structural feature disclosed as being essential to utility of the invention, In re Harnisch, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Since the members of the group do not share a substantial structural feature disclosed as being essential to utility of the invention, the group as claimed fails the Harnisch test and the claims are not accorded Markush restriction practice because they do not meet the requirements to be accorded Markush practice under MPEE 803.02.

VI. Claims 2-8, drawn to a method for detecting a cell proliferative disorder in a human subject comprising contacting a cellular component from said subject with an antibody directed against RCCA-1 or immunogenic fragment thereof, which binds to a cellular component associated with a cell proliferative disorder, and detecting whether or not the antibody binds to the cellular component, classified in class 435, subclass 7.1.

VII. Claims 2-8, drawn to a method for detecting a cell proliferative disorder in a human subject comprising contacting a cellular component from said subject with an antibody directed against RCCA-2 or immunogenic fragment thereof, which binds to a cellular component associated with a cell proliferative disorder, and detecting whether or not the antibody binds to the cellular component, classified in class 435, subclass 7.1.

VIII. Claims 2-8, drawn to a method for detecting a cell proliferative disorder in a human subject comprising contacting a cellular component from said subject with an antibody directed against RCCA-3 or immunogenic fragment thereof, which binds to a cellular component associated with a cell proliferative disorder, and detecting whether or not the antibody binds to the cellular component, classified in class 435, subclass 7.1.

IX. Claims 2-8, drawn to a method for detecting a cell proliferative disorder in a human subject comprising contacting a cellular component from said subject with an antibody directed against RCCA-4 or immunogenic fragment thereof, which binds to a cellular component associated with a cell proliferative disorder, and detecting whether or not the antibody binds to the cellular component, classified in class 435, subclass 7.1.

X. Claims 2-8, drawn to a method for detecting a cell proliferative disorder in a human subject comprising contacting a cellular component from said subject with an antibody directed against RCCA-5 or immunogenic fragment thereof, which binds to a cellular component associated with a cell proliferative disorder, and detecting whether or not the antibody binds to the cellular component, classified in class 435, subclass 7.1.

XI. Claim 9, drawn to an antibody directed against RCNL-1 or immunogenic fragment thereof, classified in class 530, subclass 387.1.

XII. Claims 10-16, drawn to a method for detecting a cell proliferative disorder in a human subject comprising contacting a cellular component from said subject with

an antibody directed against RCNL-1 or immunogenic fragment thereof, which binds to a cellular component associated with a cell proliferative disorder, and detecting whether or not the antibody binds to the cellular component, classified in class 435, subclass 7.1.

It is noted for Applicant's convenience although the claims are presented in Markush format, the claims are drawn to multiple agents and methods using multiple agents which do not share, as a whole, a substantial structural feature disclosed as being essential to their utility. Thus, the analysis of the claims, for restriction purposes, is subject to the findings of the court wherein the court found that unity of invention exists where entities included within a Markush group share a substantial structural feature disclosed as being essential to utility of the invention, In re Harnisch, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Since the members of the group do not share a substantial structural feature disclosed as being essential to utility of the invention, the group as claimed fails the Harnisch test and the claims are not accorded Markush restriction practice because they do not meet the requirements to be accorded Markush practice under MPEP 803.02.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions of Groups I-V and XI are directed to related antibodies that bind nuclear matrix proteins. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j).

In the instant case, the inventions as claimed the inventions are distinct because the biological processes involved in antibody generation are variable and unpredictable in nature. It is the structural differences generated by these processes that allow the antibodies to recognize different epitopes. It is unlikely that any two antibodies, even those directed to the same epitope, have the same structure. Thus, the inventions of the Groups I-V and XI are distinct. Since the products are distinct searching all of the claims of both groups would invoke a burdensome search. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

4. Inventions VI-X and XII are directed to related methods. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j).

In the instant case, the inventions of Groups VI-X and XII as claimed are distinct because each method employs a distinct antibody to perform the method as claimed. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

5. Inventions of Group I and Group VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product. See MPEP § 806.05(h). In the instant case, the RCCA-1 antibody could be use for immunoaffinity chromatography.

6. Inventions of Group II and Group VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the RCCA-2 antibody could be use for immunoaffinity chromatography.

7. Inventions of Group III and Group VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the RCCA-3 antibody could be use for immunoaffinity chromatography.

8. Inventions of Group IV and Group IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the RCCA-4 antibody could be use for immunoaffinity chromatography.

9. Inventions of Group V and Group X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the RCCA-5 antibody could be use for immunoaffinity chromatography.

10. Inventions of Group XI and Group XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the RCNL-1 antibody could be use for immunoaffinity chromatography.

11. Inventions of Group I and Groups VII-X and XII are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the antibody of Group I cannot be used in the methods of Group VII-X and XII because it is not directed to the protein to be detected by these methods.

12. Inventions of Group II and Groups VI, VIII-X, and XII are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the antibody of Group II cannot be used in the methods of Group VI, VIII-X, and XII because it is not directed to the protein to be detected by these methods.

13. Inventions of Group III and Groups VI, VII, IX, X and XII are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the

product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the antibody of Group III cannot be used in the methods of Group VI, VII, IX, X and XII because it is not directed to the protein to be detected by these methods.

14. Inventions of Group IV and Groups VI-VIII, X, and XII are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the antibody of Group IV cannot be used in the methods of Group VI-VIII, X, and XII because it is not directed to the protein to be detected by these methods.

15. Inventions of Group V and Groups VI-IX and XII are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the antibody of Group V cannot be used in the methods of Group VI-IX and XII because it is not directed to the protein to be detected by these methods.

16. Inventions of Group XI and Groups VI-X are directed to an unrelated product and process. Product and process inventions are unrelated if it can be shown that the product cannot be used in, or made by, the process. See MPEP § 802.01 and § 806.06. In the instant case, the antibody of Group XI cannot be used in the methods of Groups VI-X because it is not directed to the protein to be detected by these methods.

17. Furthermore, searching all of the inventions of Groups I-XII would invoke a burdensome search. Some of the inventions have been classified separately. Thus, each of these inventions has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. Although some of the inventions are classified similarly, classification of subject

matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not coextensive and is much more important in evaluating the burden of search.

Because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

18. Species Elections for Groups VI-X

A. Claim 2 is generic to the following disclosed patentably distinct species of cellular component:

1) protein

2) not protein

B. Claim 2 is generic to the following disclosed patentably distinct species of where the cellular component is taken from:

1) subject's kidney

2) not the subject's kidney

C. Claim 2 is generic to the following disclosed patentably distinct species of label:

1) radioisotope

2) bioluminescent compound

3) a chemiluminescent compound

4) fluorescent compound

5) metal chelate

6) enzyme

19. Species Elections for Groups XII

A. Claim 10 is generic to the following disclosed patentably distinct species of cellular component:

1) protein

2) not protein

B. Claim 10 is generic to the following disclosed patentably distinct species of where the cellular component is taken from:

1) subject's kidney

2) not the subject's kidney

C. Claim 10 is generic to the following disclosed patentably distinct species of label:

1) radioisotope

2) bioluminescent compound

3) a chemiluminescent compound

4) fluorescent compound

5) metal chelate

6) enzyme

20. The above species are independent or distinct because they comprise structurally distinct molecules and have different modes of operation and different effects. Further, each species would require different searches and the consideration of different patentability issues.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each of group A,B, and C for the elected Group even though this requirement is traversed. Applicant is

advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

21. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined

claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

22. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

21. Applicant is advised that the reply to this restriction requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

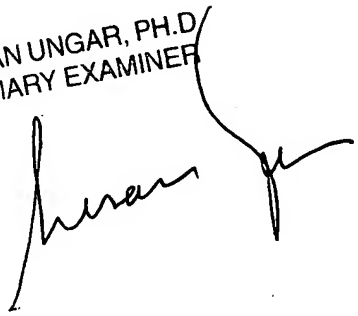
23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Reddig whose telephone number is (571) 272-9031. The examiner can normally be reached on M-F 8:30 a.m.-5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Peter J. Reddig, Ph.D.
Examiner
Art Unit 1642

SUSAN UNGAR, PH.D
PRIMARY EXAMINER



PJR